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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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WASHINGTON DC 20007-0010

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

07/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/722,438

Applicant(s)

COTREL ET AL.

Examiner

Mark L. Berch

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-68 is/are pending in the application.
- 4a) Of the above claim(s) 5-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 57-68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/124,651.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

With regard to the summary data sheet page 8-108, the examiner notes that the isomers are labeled as R and S, and it is impossible to tell which is the dextro. Regardless, the test of Median Lethal Dose is a different test and reflects toxicity at a much higher dosage. Indeed, it is not unreasonable for two different compounds to have different relative toxicities when measured at different dosages.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura, Houghton, Musch or Cotrel '149.

The references disclose Zopiclone and compositions thereof. Both the d and l forms will be present as components of the prior art racemic mixture, and hence the d compound is old. Patenting a component of an old mixture requires some purity limitation, *In re Bergstrom*, 166 USPQ 256.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

Art Unit: 1624

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-62, 64-65, 67-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ✓1. The term "chlorohydrate" in claims 58, 61 is mistaken. There is no such salt; the term "hydrochloride" is what the specification has.
- ✓2. Likewise with "tartate". It should be "tartrate".
- ✓3. The "and" in claim 57, line 2 should technically be "or". Note the use of "or" in next to last line of claim 63.
4. It is unclear what the last two choices are in claim 59. Is the last one a specific acid or a group of acids --- note that the locants are missing on the naphthylene ring, and it is not clear what is β to what. Is this the salt of an acid or an alcohol? Likewise for the next to last term.
5. Claim 60 appears to be intended as a composition claim, but there is no carrier recited. A proper pharmaceutical composition requires a carrier. It's not clear what the difference is, if any, between claim 60 and claim 63.
6. It is unclear what is intended by "additive" in claim 67. Everything else in the markush groups is already an additive, so what are these other items needed for? It appears that applicants actually intend a narrower definition of "additive", one which does not include "lubricant", "sweetener" etc., but what is that definition?

Claims 67-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A. The “combinations thereof” lacks description in the specification. For example, the claim 68 list appears at page 5, lines 20-22, but “combinations” isn’t present.

B. The term “aromatic”, i.e. something to provide aroma such a perfume, lacks description in the specification.

C. The term “additive” is broader than the specification, which has “adjuvant”. An adjuvant is a substance that, when added to a medicine, speeds or improves its action. As such, it is a narrower concept than “additive”, which is merely something added. For example, a colorant would be an additive, but not an adjuvant.

Claims 59, 62, and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The last terms in these claims lacks description in the specification. As worded, the oxy is a divalent group, so that the methylene is connected to two oxygen atoms, one on each naphthyl. The term in the specification is unclear, but it does say “hydroxy”, which means the OH group. In other words, the term in the specification is an alcohol. The current term in the claim is an ether.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

July 6, 2001